U.S. Food and Drug Administration
FDA Talk Paper

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available.

T01-30
July 25, 2001

Print Media: 301-827-6242
Broadcast Media: 301-827-3434
Consumer Inquiries: 888-INFO-FDA

FDA STRENGTHENS WARNINGS FOR OXYCONTIN

FDA has strengthened the warnings and precautions sections in the labeling of OxyContin (oxycodone HCl controlled-release) Tablets, a narcotic drug approved for the treatment of moderate to severe pain, because of continuing reports of abuse and diversion.

OxyContin contains oxycodone HCL, an opioid agonist with an addiction potential similar to that of morphine. Opioid agonists are substances that act by attaching to specific proteins called opioid receptors, which are found in the brain, spinal cord, and gastrointestinal tract. When these drugs attach to certain opioid receptors in the brain and spinal cord they can effectively block the transmission of pain messages to the brain.

OxyContin is a controlled substance in Schedule II of the Controlled Substances Act (CSA), which is administered by the Drug Enforcement Administration (DEA). Schedule II provides the maximum amount of control possible under the CSA for approved drug products.

In recent months, there have been numerous reports of OxyContin diversion and abuse in several states. Some of these reported cases have been associated with serious consequences including death. In an effort to educate health care providers about these risks, Purdue Pharmaceuticals, manufacturer of the product, has issued a warning in the form of a "Dear Healthcare Professional" letter. The "Dear Healthcare Professional" letter will be distributed widely to physicians, pharmacists, and other healthcare professionals. The letter explains

the changes to the labeling including proper prescribing information and highlights the problems associated with the abuse and diversion of OxyContin.

OxyContin, like morphine, has a high potential for abuse. It is supplied in a controlled-release dosage form and is intended to provide up to 12 hours of relief from moderate to severe pain. The tablet must be taken whole and only by mouth. When the tablet is crushed and its contents are injected intravenously or snorted into the nostrils, the controlled release mechanism is defeated and a potentially lethal dose of oxycodone is released immediately.

FDA has worked with Purdue to make specific changes to the OxyContin labeling. The new labeling is intended to change prescription practices as well as increase the physicians' focus on the potential for abuse, misuse, and diversion.

Changes include a "black box warning", the strongest type of warning for an FDA-approved drug. The new warnings are intended to lessen the chance that OxyContin will be prescribed inappropriately for pain of lesser severity than the approved use or for other disorders or conditions inappropriate for a Schedule II narcotic.

The FDA-approved indication for OxyContin is for the treatment of patients with moderate to severe pain who are expected to need continuous opioids for an extended time. An important factor that must be considered in prescribing OxyContin is the severity of the pain that is being treated, not simply the disease causing the painful symptoms.

FDA continues to recommend that appropriate pain control be provided to patients who are living with severe pain. Although abuse, misuse, and diversion are potential problems for all opioids, including OxyContin, opioids are a very important part of the medical armamentarium for the management of pain when used appropriately under the careful supervision of a physician.

Because of the ongoing problem of OxyContin abuse and diversion, FDA has met with DEA, the Substance Abuse and Mental Health Service Agency, the National Institute on Drug Abuse, Purdue, Inc., and others. FDA will continue to monitor reports of abuse, misuse, and diversion of OxyContin and other opioids and will work with other federal agencies and drug manufacturers to help ensure that these important drugs remain available to appropriate patients.

Since all opioids are subject to abuse, misuse, and diversion, FDA is encouraging all manufacturers of opioids sold in the U.S. to review voluntarily, and revise as necessary, their product's labeling to provide adequate warnings and precautions regarding these risks and to promote responsible prescribing practices.

For more information, patients and healthcare providers can call Purdue Pharmaceuticals at 1-888-726-7535, or go to FDA's website at www.fda.gov/cder/drug/infopage/oxycontin/.

FDA News Page | **FDA Home Page**

Office of Public Affairs
Hypertext uploaded by clb 2001-JUL-25.